

Notice of Allowability

Application No.

10/792,355

Examiner

Rei-tsang Shiao, Ph.D.

Applicant(s)

PFEIFFER ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed on February 12, 2007.
2. ☒ The allowed claim(s) is/are 14-15 and 17-21, now are 1-7.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

1. This application claims benefit of the foreign applications:
FRANCE 00/08793 with a filing date 07/06/2000; FRANCE PCT/FR01/02167 with a filing date 07/06/2001.
2. Amendment of claim 23 in the amendment filed on February 12, 2007, is acknowledged. Claims 14-26 are pending in the application.

Responses to Arguments

3. Applicant's arguments regarding the rejection of claims 25-26 over Guez et al. US 6,653,336 under 35 U.S.C. 102(e) filed on February 12, 2007, have been fully considered and they are not persuasive. It is noted that Guez et al. disclose the same solid pharmaceutical composition (i.e., tablet) comprising a diuretic indapamide. The rejection of claims of 25-26 over Guez et al. '336 under 35 U.S.C. 102(e), is maintained.
4. Applicant's arguments regarding the provisional rejection of claims 23 and 25-26 under the obvious-type double patenting over Pfeiffer et al. co-pending application No. 11/052,489 in view of Brittain's publication filed on February 12, 2007, have been fully considered and they are not persuasive. Applicants are requested to disclose the instant pharmaceutical composition does not render obviousness of Pfeiffer et al. in terms of mechanic benefits. A side-by-side comparison between the instant pharmaceutical composition and Pfeiffer et al. after the processes of preparation is needed to overcome the obviousness. The provisional rejection of claims 23 and

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25-26 under the obvious-type double patenting is maintained, and applicants are requested to file a terminal disclaimer to overcome the rejection.

5. Applicant's arguments regarding the rejection of claims 23 and 25-26 under 35 U.S.C. 112, first paragraph filed on February 12, 2007, have been fully considered and they are not persuasive. It is well recognized in the art that process of preparing pharmaceutical composition will produce the thermodynamically stable form of crystals, thus, the instant α crystalline form, after mixing, grinding, compressing would be transformed into a thermodynamically stable form(s). Applicants are requested to disclose that the instant pharmaceutical composition comprising α crystalline form is stable, and not changing to another form, after the processes of pharmaceutical preparation.

6. Applicant's arguments regarding the rejection of claims 14, 23 and 25-26 under 35 U.S.C. 102(b) or 103(a) over Guez et al. WO 99/25374 filed on February 12, 2007 have been fully considered and they are persuasive, in part. Since the instant α crystalline form with X-ray diffraction data has not been disclosed, the rejection of claim 14 under 35 U.S.C. 102(b) or 103(a) over Guez et al. WO 99/25374 has been withdrawn herein. However, the instant pharmaceutical compositions of claims 23 and 25-26 still render obviousness of Guez et al., the rejection of claims 23 and 25-26 under 35 U.S.C. 102(b) or 103(a) over Guez et al. is maintained.

EXAMINER'S AMENDMENT

7. An examiner's amendment to the record appears below. Should the

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changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with G. Patrick Sage on July 12, 2007. The application has been amended as follows:

In claim 14, after the last line (i.e.,

29.213	3.05	117	2.7
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insert

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Delete claims 16 and 22-26

Reasons for Allowance

8. The following is an examiner's statement of reasons for allowance:

Claim 14 is allowable. Claims 15 and 17-21 is previously withdrawn from consideration as a result of a restriction requirement, require all the limitations of an allowable claim. Pursuant to the procedures set forth in MPEP § 821.04(a), **the restriction requirement among inventions groups, as set forth in the Office action mailed on December 01, 2005, is hereby withdrawn** and claims 15 and 17-21 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. In view of the withdrawal of the restriction requirement, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the

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provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 14-15 and 17-21 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. This invention relates to New alpha crystalline form of perindopril tert-butylamine salt. The closest reference is Guez et al. WO 99/25374, which disclose combination of hypertension converting enzyme inhibitor with a diuretic for treating microcirculation disorders. The difference between the reference and instant claims is that the instant alpha crystalline form of perindopril tert-butylamine salt has not been found. A suggestion for modification of above reference to obtain the instant crystalline form of formula (I) and their processes of making has not been found. Claims 14-15 and 17-21 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rei-tsang Shiao, Ph.D.
Patent Examiner
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July 13, 2007